Administrative Rules Montana

Department of Public Health and Human Services

Chapter 110

Subchapter 8

DRINKING WATER

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37.110.801 DRINKING WATER

- (1) Any person engaged in the production, packaging, manufacturing or processing of drinking water, culinary bottled water, or water otherwise processed and packaged for human consumption, is subject to the licensing requirements of 50-50-201, MCA, for food manufacturing establishments. Any manufacturing or bottling plant located in a state, territory, or nation other than Montana that prepares water in bottles or other containers for drinking or culinary purposes for sale in Montana must also be licensed by the department.
- (2) Each food manufacturing establishment in Montana where water is prepared for sale in bottles or other containers for human consumption and the sources of all such water must be inspected at least once each year by the local health officer, sanitarian or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction. A copy of each inspection must be submitted to the department within 30 days after the inspection occurs.
- (3) Each food manufacturing establishment in Montana where water is prepared for sale in bottles or other containers for human consumption must:
- (a) obtain its water from a community public water system approved by the water quality division of the department of environmental quality, or, if water is obtained from a separate or independent system, that system must comply with the statutes governing public water supplies, 75-6-101 et seq., MCA, the rules governing public water supplies, ARM 17.38.201 et seq., and the rule governing plans for public water supplies or wastewater systems, ARM 17.38.101.
- (b) maintain sampling records demonstrating compliance with the bacteriologic, chemical and radiologic sampling requirements specified in (6) (b) of this rule for at least 12 months after the date of sampling.
- (4) The operation of all food manufacturing establishments involved in producing, packaging, manufacturing, or processing drinking or bottled water and the products marketed must comply with these rules and with the Montana Food, Drug and Cosmetic Act, <u>50-31-101</u> et seq., MCA; the food manufacturing establishment rules, ARM <u>37.110.301</u> et seq.; the federal standards regarding food labeling, 21 CFR 101; the federal quality standards for foods with no identity standards, 21 CFR 103; the federal standards for processing and bottling of bottled drinking water, 21 CFR 129; and the Fair Packaging and Labeling Act, 15 USC 1451 et seq.
- (5) Every food manufacturing establishment desiring to sell, market or distribute bottled water in Montana, whether located in Montana or not, must apply for a license on a form provided by the department, which must be signed by the owner or the owner's legal representative, and must submit the fee required by 50-50-206, MCA. Such fee must be payable

to the department and the application must be postmarked no later than midnight on December 31 of each year. Submission of a renewal application and fee after this time will require the food manufacturing establishment to submit the late fee required by <u>50-50-206</u>, MCA. The license year is January 1 through December 31.

- (6) In addition to the fee, the late fee, if applicable, and the application form identified in (5) above, the food manufacturing establishment must submit the following to the department for review:
- (a) A certification affidavit from the state or local health officer, sanitarian or sanitarian-intraining employed by or contracted with the local board of health having jurisdiction, affirming that the establishment meets the requirements of 21 CFR 103 and 129;
- (b) If the source water is not mineral water, copies of the most recent inorganic, volatile organic, organic chemical and radiological analyses of the establishments water showing compliance of the source water with the maximum contaminant levels for regulated water systems as required by 40 CFR 141; or a certification affidavit from the state or local health officer, sanitarian, or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction, affirming that the water source complies with these standards;
- (c) Test results for pesticides and synthetic organic chemicals, if the department determines such tests are necessary or if random testing has shown there is or may be contaminants present at levels which may adversely affect public health;
- (d) A copy, photocopy, or printer's proof of each label for each product to be marketed and for each size to be marketed;
- (e) A description of the source of the water, water treatment used, all substances added to the water, and any other documentation required by the department to verify that labels and terminology used on the labeling conform with applicable law; and
- (f) For products labeled "mineral water" or for a label containing the term "mineral water", copies of the results of laboratory testing of mineral content and total dissolved solids (TDS) of the product, obtained during the 12 months preceding the license year from an agency approved to test drinking water by the department or another public health agency.
 - (7) (a) The department hereby adopts by reference:
 - (i) ARM 37.110.301 et seq., setting standards for food manufacturing establishments;
 - (ii) ARM <u>37.110.201</u> et seq., setting standards for public water supplies;
 - (iii) ARM <u>17.38.101</u>, governing plans for public water supplies;
 - (iv) 21 CFR 101, setting food labeling standards;
 - (v) 21 CFR 103, setting quality standards for foods with no identity standards;
 - (vi) 21 CFR 129, setting standards for processing and bottling bottled drinking water;
 - (vii) 40 CFR 141, containing maximum contaminant levels for drinking water, and
 - (viii) 15 USC 1451 et seq., containing federal law on packaging and labeling.
- (b) Copies of these statutes and rules may be obtained, upon payment of copying costs, from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951.

History: Sec. <u>50-31-104</u>, <u>50-31-201</u> and <u>50-50-103</u>, MCA; <u>IMP</u>, Sec. <u>50-31-104</u>, <u>50-31-201</u> and <u>50-50-103</u>, MCA; <u>NEW</u>, 1994 MAR p. 2832, Eff. 10/28/94; <u>AMD</u>, 1995 MAR p. 368, Eff. 3/17/95; TRANS, from DHES, 2001 MAR p. 2423.